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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,045	06/30/2006	Alessandro Moretta	INN-133	6062

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
02/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,045	MORETTA ET AL.	
	Examiner	Art Unit	
	MARIANNE DIBRINO	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-87* is/are pending in the application.

4a) Of the above claim(s) *78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-77 and 79-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/24/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 9/24/09 is acknowledged and has been entered.

2. Applicant' is reminded of Applicant's election without traverse of the Invention of Group I and the species of isolated antibody DF200, a detectable moiety, IL-2 as the additional component, and antibody that binds to KIR2DL1 and KIR2DL2/3 and neutralizes KIR mediated inhibition of NK cell cytotoxicity, in Applicant's amendment filed 4/24/09

Claims 70, 71, 77, 79, 80 and newly added claim 87 read upon the elected species.

Upon consideration of the prior art, examination has been extended to include the species of Fab, Fab', humanized and chimeric which are recited in instant claims 70, 72-76, 79 and 82-86.

Claims 70-77, and 79-87 are presently being examined.

3. Applicant's response (specifically, the Declaration of Frank Christopher Eisenschenk, Ph.D., filed 9/24/09) has overcome the prior rejection of record of claims 70, 71, 77, 79 and 80 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

4. Applicant's response filed 9/24/09 has overcome the prior rejection of record of claim 80 under 35 U.S.C. 102(e) as being anticipated by US 2005/0037002 A1. Applicant's argument is found persuasive, *i.e.,* the parent provisional application 60/489489 filed on July 23, 2003 of the art reference US 2005/0037002 A1 does not provide support for administering a composition comprising the art antibody along with IL-2.

5. For the purpose of prior art rejections, the filing date of the instant claims 70-77 and 79-87 is deemed to be the filing date of the 60/545,471 provisional parent application, *i.e.,* 2/19/04, as the other provisional parent application 60/483,894 does not provide support for the claimed limitations of the instant application. 60/483,894 does not provide support for Fab', Fab'-SH, nor wherein the composition recited in instant claim 80 further comprises IL-2.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 70-77, 79 and 81-87 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0037002 A1 (of record, has priority to 7/24/03).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US 2005/0037002 A1 discloses making antibodies or fragments (such as human, humanized, chimeric, and fragments of these such as Fab or Fab'2) thereof that block the KIR2DL receptors of NK cells by: (1) immunizing a non-human mammal, including a mouse, rat, bovine, porcine, horse, rabbit, goat, sheep or XENOMOUSE, with an immunogen comprising a KIR2DL polypeptide, including one on the surface of an NK cell, (2) preparing monoclonal antibodies from the said immunized animal, wherein said monoclonal antibodies bind said KIR2DL polypeptide, (3) selecting monoclonal antibodies from step (2) that cross react with at least two different serotypes of KIR2DL polypeptides, and (4) selecting monoclonal antibodies of (3) that inhibit KIR2DL-mediated inhibition of NK cells, such as KIR2DL-mediated inhibition of NK cytotoxicity, and additionally selecting and isolating an antibody that binds to a human (*i.e.,* a primate) NK cell and to KIR2DL1 and KIR2DL2/3. US 2005/0037002 A1 discloses that the antibodies preferably bind a common determinant of KIR2DL human receptors such as KIR2DL1 and KIR2DL2/3, and that the monoclonal antibody is DF200, binds to the same epitope as DF200 or competes for binding with DF200. US 2005/0037002 A1 discloses that the antibody may be an antigen-binding fragment of one of the aforementioned antibodies. US 2005/0037002 A1 also discloses that the antibody used for therapy may have a human or non-human primate IgG1 or IgG3 Fc portion. US 2005/0037002 A1 discloses that the inhibitory antibody (such as DF200) or fragment thereof may be administered with a therapeutic antibody in order to treat cancer by enhancing ADCC of the therapeutic antibody (see entire reference, especially [0022], [0053]-[0055], [0062], [0073][0075], [0079]-[0082], [0087]-[0088], [0096], [0100], [0104], [0125]-[0129], Examples).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 70-77 and 79-87 are rejected under 35 U.S.C. 103(a) as being obvious over US 2005/0037002 A1 (of record) in view of Eisenthal *et al* (J. of Immunol. 1990, 144: 4463-4471).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US 2005/0037002 A1 discloses making antibodies or fragments (such as human, humanized, chimeric, and fragments of these such as Fab or Fab'2) thereof that block the KIR2DL receptors of NK cells by: (1) immunizing a non-human mammal, including a mouse, rat, bovine, porcine, horse, rabbit, goat, sheep or XENOMOUSE, with an immunogen comprising a KIR2DL polypeptide, including one on the surface of an NK cell, (2) preparing monoclonal antibodies from the said immunized animal, wherein said monoclonal antibodies bind said KIR2DL polypeptide, (3) selecting monoclonal antibodies from step (2) that cross react with at least two different serotypes of KIR2DL polypeptides, and (4) selecting monoclonal antibodies of (3) that inhibit KIR2DL-mediated inhibition of NK cells, such as KIR2DL-mediated inhibition of NK cytotoxicity, and additionally selecting and isolating an antibody that binds to a human (*i.e.,* a primate) NK cell and to KIR2DL1 and KIR2DL2/3. US 2005/0037002 A1 discloses that the antibodies preferably bind a common determinant of KIR2DL human receptors such as KIR2DL1 and KIR2DL2/3, and that the monoclonal antibody is DF200, binds to the same epitope as DF200 or competes for binding with DF200. US 2005/0037002 A1 discloses that the antibody may be an antigen-binding fragment of one of the aforementioned antibodies. US 2005/0037002 A1 also discloses that the antibody used for therapy may have a human or non-human primate IgG1 or IgG3 Fc portion. US 2005/0037002 A1 discloses that the inhibitory antibody (such as DF200) or fragment thereof may be administered with a therapeutic antibody in order to treat cancer by enhancing ADCC of the therapeutic antibody (see entire reference, especially [0022], [0053]-[0055], [0062], [0073][0075], [0079]-[0082], [0087]-[0088], [0096], [0100], [0104], [0125]-[0129], Examples).

US 2005/0037002 A1 can not be relied upon to the filing date (*i.e.,* 7/24/03) of its parent provisional application (*i.e.,* 60/489,489) for the teaching that the antibody composition further comprises IL-2 (*i.e.,* the limitation recited in instant claim 80).

Eisenthal *et al* teach that administration of appropriate cytokines such as IL-2 may be a useful adjunct to the administration of mAb for the treatment of cancer in humans, by increasing ADCC, Including that mediated by NK cells (see entire reference, especially abstract and introduction sections).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included IL-2 as taught by Eisenthal *et al* in the antibody composition taught by US 2005/0037002 A1.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to make a composition that could increase ADCC in order to treat cancer.

In addition, the motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Section MPEP 2144.07.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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